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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,957	PETROSENKO ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16,19,23-25 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-16,19,23-25 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-7, 9-16, 19, 23-25 and 27-29 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims. However examiner will address the essence of applicant's arguments herein. As to the argument that Lockwood does not disclose a wound dressing member having a plurality of holes, Lockwood discloses a wound dressing 222 in association with the embodiment of Fig. 27 that defines through holes defined at the termini of channels 56 and a port 51 in communication with the holes via those channels. As to the argument that the cover 52 of Lockwood is not configured to engage at least a portion of the wound surface, the cover 52 would overlay the funnel portion of insert 219. As the wound in Fig. 27 is a tunneled wound 116, the cover 52, being larger than the wound diameter, necessarily is configured to engage at least a portion of the wound surface, Especially upon application of suction as is depicted for example in Fig. 40. It is examiner's position this contact is due to suction and would still occur with the tunneled wound of Fig. 27. AS to the argument that Lockwood does not disclose bores extending from one side surface to another, applicant is reminded that the claim reads as follows: "the passageways comprise bores through the body extending from one side surface to another". As Lockwood clearly meets this limitation as illustrated in Figs. 4 and 5, Lockwood discloses such bores extending from one side surface to another.

2. Applicant's arguments, see Remarks, filed January 23, 2009, with respect to the rejection of claims 1, 13, 14, 16, 19, 23-25, and 27-29 under 35 U.S.C. 102 as anticipated by LaMere have been fully considered and are persuasive. However, new grounds of rejection have been made in view of newly found prior art references.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on April 22, 2009 was filed after the mailing date of the non-final action on September 30, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 9, 12-14, 16, 19 and 23-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Lockwood *et al.* (WO 02/43634 A2).

With respect to **claim 1:** Lockwood teaches a vacuum bandage system 10, 12 for use with a wound 16 having a wound surface. The vacuum bandage system 10, 12 comprises the following: a wound dressing member 220 similar to made generally of a non-porous material, namely medical-grade silicone, configured to engage at least a portion of the wound surface of the wound 16, having a plurality of holes 28 and a port 26 in communication with the holes and capable of being coupled to a vacuum source 12 (Fig. 27, Page 12, lines 3-6, 16-21); a wound insert 219 capable of, and thus configured for, placement within the wound 16 between the wound surface 18 and the wound dressing member 220, the insert 219 being made of a

material which is not porous or foam-like (Page 11, lines 19-21, Page 22, line 27 - Page 23, line 14); and a cover 222 capable of, and thus configured for, placement over the wound dressing member 220 to seal about the wound 16 and create a sealed environment between the wound 16 and the cover 62 in which negative pressure can be established. (Figs. 3, 7 & 15) With regard to the limitation "to engage healthy skin surrounding the wound in order to seal about the wound", Lockwood meets the limitation regarding a cover that seals about the wound and thus is fully functional to engage healthy skin surrounding the wound.

With respect to **claim 2:** Lockwood teaches that the generally non-porous material of insert 20 comprises medical grade silicone. (Page 11, lines 16,17)

With respect to **claim 3:** Lockwood teaches that the wound insert 219 is flexible in that it is made from medical grade silicone similar to insert 19 and is considered herein by examiner to also be "thin" due to its small radial dimension. The insert includes a plurality of discrete passageways 56 in communication with the vacuum source 14/110. (Page 23, lines 2-4)

With respect to **claim 4:** Lockwood teaches that the passageways 56 are conduits through the wound insert 20. (Page 23, lines 2-4)

With respect to **claim 5:** Lockwood teaches that the insert is cylindrical in shape and thus necessarily includes a top surface, a bottom surface, and a side surface, wherein the conduits 56 form holes or bores in one or more of the side surfaces, and wherein the insert 219 further includes holes 36 in communication with the conduits 28/56 and forming holes 36 in one or more of the top and bottom surfaces 22, 24. (see Lockwood, fig. 7, supra).

With respect to **claim 6:** Lockwood teaches an insert 20 that includes a top surface 24, a bottom surface 22, wherein the passageways 28, 30, 32, 34 comprise channels in each of the top and bottom surfaces 22, 24.

With respect to **claim 9:** The insert 219 disclosed by Lockwood in Fig. 27 is cylindrical in shape.

With respect to **claim 12:** Lockwood teaches a wound insert 20 for use with a vacuum bandage 10 having a suction tube coupled to a vacuum source and a wound dressing member 52 coupled to a wound 16 and including a tube port receiving the suction tube. The insert 20 comprises the following: a thin flexible member 20 including a plurality of discrete passageways 28, 30, 32, 34, 36 in communication with the vacuum bandage 10 and source 14/110. (Page 11, lines 15, 16, Page 12, lines 16-26) The thin flexible member 20 is spaced away from the suction tube having bores 36 extending from one side surface to another and extending from the top surface to the bottom surfaces 22, 24. (Fig. 3)

With respect to **claim 13:** Lockwood discloses a wound insert 219 for use with a vacuum bandage including a wound dressing member 220 coupled to a wound 116, a port 51 of the wound dressing member 220, and a tube 13 coupled to the port 51 and to a vacuum source 12 (Fig. 27, Page 25, lines 7-10), the wound insert 219 being positioned between the vacuum bandage 220 and a wound surface 18 of the wound. The wound insert 219 comprises the following: a body made of a generally non-porous, flexible material, namely medical grade silicone, wherein the body is cylindrical in shape (Fig. 27), wherein a height of the cylindrical

body is substantially greater than a diameter of the cylindrical body owing to its cylindrical shape, and further wherein the body includes a solid top surface and a solid bottom surface.

With respect to **claim 14:** The body, insert 219, disclosed by Lockwood is considered herein to be generally rod-shaped inasmuch as it is also cylindrically shaped. (Fig. 27)

With respect to **claim 16:** The body 219 disclosed by Lockwood includes discrete passageways 56. (Page 23, 4-6)

With respect to **claim 19:** The body 219 disclosed by Lockwood is made of a generally non-adhesive material, namely medical-grade silicone.

With respect to **claim 24:** The wound insert 219 disclosed by Lockwood includes a rod-shaped wound insert. (Fig. 27)

With respect to **claim 25:** The wound insert is made of a generally non-porous material, namely medical grade silicone. It is examiner's position that because medical-grade silicone is non-foam-like, which is applicant's disclosed definition for the phrase "generally non-porous", the material of insert 219 is generally non-porous.

With respect to **claim 23:** Lockwood discloses a wound insert 20 that is capable of, and thus configured to, preventing an ulcerated portion of a wound from forming a bridge to another ulcerated portion of the wound inasmuch as it occupies the space between wound edges and unhealed/ulcerated portions of the wound where granulation would otherwise occur and form a bridge between ulcerated portions of the wound.

5. Claims 7, 11, 15, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al ('634) in view of Gibertoni (EP 1,190,732 A1).

With respect to **claim 7:** The insert 219 disclosed by Lockwood does not further include holes 36 between the channels 56. Gibertoni discloses a wound insert member having both channels 12 and holes in the form of external slits 15. Gibertoni discloses that the holes/slits 15 effect drainage by capillary action which aids the drainage occurring through the channels 12. ('732, Abstract) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Lockwood such that the wound insert further includes holes between the channels and top and bottom surfaces so as to effect drainage by capillary action that supplements the drainage occurring through the channels for quicker draining and healing.

With respect to **claims 11,15:** Applicant has not clearly and explicitly defined the bounds of the recited range "approximately 0.0925 inch (2.35 mm)", therefore the claim is given its broadest reasonable interpretation. Lockwood does not disclose a particular diameter for the insert 219. Gibertoni discloses a diameter of 2.3 mm, which is considered herein to satisfy the limitation of "approximately 0.0925 inch (2.35 mm)." Gibertoni discloses that such a diameter is a preferred diameter in association with other specifications of the body to effect preservation of drainage via capillary action. Since the device of Gibertoni seeks to solve a similar problem to that with which the applicant's invention is concerned, it would be obvious to one of ordinary skill in the art to modify the device of Lockwood such that the insert has a diameter as disclosed by Gibertoni with a reasonable expectation of success to facilitate drainage by virtue of the diameter itself or potentially in combination with other structural elements of the device.

With respect to **claim 28:** Lockwood does not disclose that the body is hollow to define a central conduit therethrough. Gibertoni discloses a wound insert body that is hollow so as to define a central conduit divided into four channels 12 therethrough. Since the device of Gibertoni seeks to solve a similar problem to that with which the applicant's invention is concerned, it would be obvious to one of ordinary skill in the art to modify the device of Lockwood such that the insert has a diameter as disclosed by Gibertoni with a reasonable expectation of success to facilitate drainage.

With respect to **claim 29:** Lockwood does not disclose that the body is hollow to define a central conduit therethrough. The body of the inset disclosed by Gibertoni further defines passageways in the form of surface slits 15 formed through the body to communicate with the central conduit. Gibertoni discloses that the holes/slits 15 effect drainage by capillary action which aids the drainage occurring through the channels 12. ('732, Abstract) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Lockwood such that the wound insert further includes holes between the channels and top and bottom surfaces so as to effect drainage by capillary action that supplements the drainage occurring through the channels for quicker draining and healing.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al in view of Hirsch et al (U.S. Patent No. 5,080,650).

With respect to **claim 10:** Lockwood discloses that the insert 219 is made of medical grade silicone but does not explicitly disclose that the insert is made of approximately 50 durometer

silicone. Hirsch discloses that the preferred durometer range for medical grade silicone is 50-80, which is a disclosure interpreted by examiner as meaning that this range was known to one of ordinary skill in the art at the time applicant's invention was made. ('650, Col. 4, lines 18-20) Thus, it would be obvious to one of ordinary skill in the art to modify the medical grade silicone disclosed by Lockwood such that it is a shore 50 durometer material as disclosed by Hirsch with a reasonable expectation of success to ensure the material is hard enough to withstand vacuum forces yet soft enough so as to not be uncomfortable to the user.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al in view of Miner et al (U.S. Patent No. 3,860,008).

With respect to **claim 27:** Lockwood does not disclose a wound insert comprising a plurality of rods. Miner discloses a wound insert comprising a plurality of rods 10 that are made of a generally non-porous, flexible material in the form of silicone rubber and that are held together by webs that are tearable to permit the rods to be separated from each other. (whole document) Miner discloses that this allows modification of insert size to reduce areas of possible infection due to an ill-fitting drain, therefore it would be obvious to one of ordinary skill in the art to modify the device of Lockwood by replacing the rod-shaped insert with the insert disclosed by Miner to allow modification of the insert size to reduce areas of possible infection by providing a better-fitting insert.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761
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